

To: Pharmacy Manager/Responsible Person From: Nevada State Board of Pharmacy Inspector

Subject: Self-Assessment/Inspection Process

A revised pharmacy inspection and assessment process allows you to know the standards anticipated in a pharmacy inspection. The enclosed forms are for pharmacy compliance and workplace self-assessment.

### To Make This Work:

- 1. Print the Retail Pharmacy Inspection Form and the Work Place Assessment found online in the corresponding month listed on the Inspection Notice you received in the mail. Have them <u>ready and available</u> for the inspector in case of your absence. The forms are:
  - A. The Retail Pharmacy Inspection form
  - B. The Work Place Assessment form
- 2. I will review the forms with you and inspect your facility during the month listed on your Inspection Notice. Your inspection will occur during normal business hours, at no specific date or time. To minimize disruption of pharmacy operations please have the following materials available at the time of inspection:
  - a. Completed 222 forms since last inspection
  - b. Most recent bi-annual inventory
  - c. In-service training records for all pharmacy technicians
  - d. Inspection report from previous year

My observations along with your findings will assure understanding and compliance with Nevada law. Failure to fill out the inspection report and assessment suggests either you are not concerned with knowing the law or complying with it.

An explanation: Pharmacy industry and the board of pharmacy have devised this assessment process to identify and understand workplace conditions. All data is confidential for analysis purposes only. The second pages of the workplace assessment afford you and other pharmacist employees to submit suggestions for improved efficiency, safety and patient care. It can be a mechanism to discuss improvements with your management and serves the board to evaluate the pharmacy environment.



NRS=NEVADA REVISED STATUTE NAC=NEVADA ADMINISTRATIVE CODE ISMP=INSTITUTE FOR SAFE MEDICATION PRACTICES @ <a href="http://www.ismp.org/communityRx/aroc/">http://www.ismp.org/communityRx/aroc/</a> Improving Medication safety in Community Pharmacy: Assessing Risk and Opportunities for Change (the cover letter must be attached to this completed form. Circle yes for compliant and no for non compliant. You may make comments as needed)

#### PHARMACY FACILITY

Is there adequate space for storage including shelves, refrigerators, narcotic cabinets/safes, and counter areas to avoid crowding?  NAC		Yes	No
2' x 3' clear work area for each pharmacist & technician on duty & minimum and 4' x 8' free floor space available behind prescription compounding area?	NAC 639.525	Yes	No
Does the pharmacy prepare sterile preparations?  If sterile compounding (preparation) is done at your facility, print at Compounding Addendum Form. The Addendum is the second part of Pharmacy Inspection Form. On the Board website Select Forms.		Yes e <b>rile</b>	No
Is there a clean and sanitary sink with hot and cold running water available in the pharmacy for all personnel to use?	NAC 639.469	Yes	No
Is the pharmacy clean and arranged in an orderly manner?	NAC 639.469	Yes	No
(The following are ISMP recommendations to improve page 1975)	practice safety)		
Arrange drug products that have similar or confusing manufacturer labeling, packaging, and/or drug names (that look or sound alike) to be clearly separated on shelves or have warnings.	ISMP		
Use a system to separate each patient order and keep multiple filled prescriptions in each order together.	ISMP		
Is the temperature in the pharmacy compatible with drug storage requirements?	NRS 639.282	Yes	No
Is the temperature in the refrigerator(s) appropriate for the medications stored?  NAC 639.527  Ye  How often is the temperature checked?		Yes	No
Is the temperature in the freezer(s) appropriate for the medications stored?  NAC 639.527  Yes		Yes	No



Have there been any issues with the refrigerator(s) or freezer(s) being out of temperature range? <circle> If Yes, have available for review the documentation of the results of the audit by the pharmacist of the safety or disposition of the medications in the refrigerator(s), freezer(s). Are the facilities sufficient to allow for patient confidentiality to be maintained during counseling? NAC 639.708 No Do all employees of the pharmacy wear an identification badge that clearly the person by their name and job position? NAC 639.542 Yes No Are current licenses and registrations displayed? NRS 639.150 Yes No Comments: **EQUIPMENT** Are fax and computer printed copies clear and legible? NAC 639.525 No Does each computer terminal require the staff member to login with a password, biometric or other electronic means of identification? NAC 639.751 Yes No Does the computer capture the identification of the staff member performing each separate task in filling a prescription? NAC 639.751 Yes No Does the computer require the entry of a password, biometric or other electronic means of identification each time there is new data entry or a change made to data? NAC 639.751 No How often are the passwords changed? NAC 639.751 Does the terminal automatically log out a staff member or does the staff member have to manually log out? NAC 639.751 <circle> Manual Automatic Is a poison control center telephone number posted in the pharmacy? NRS 454.130 No Current references available <circle> (electronic) (printed) NAC 639.503 Yes No Current Nevada Pharmacy Law Book (printed) NAC 639.503 Yes No



Does all equipment such as the phone, fax, computer, computer printer, electronic signature devices work properly?  NAC 639.469  Yes					No	
Does the pharm (circle all that y	acy have adequate you have)	e equipment for c	ompounding?	NAC 639.525	Yes	No
Manual Scale	Weights	Electronic Scale	Graduates	Filler Tube (fillmaster, reconstitube,	other)	
If non-sterile compounding (preparation) is done at your facility, print and complete the Non-Sterile Compounding Addendum Form found on the Board website. Select Forms. If the pharmacy is not required to complete the form, your pharmacy still must comply with all Nevada Statutes and Administrative code when compounding non-sterile products.					n-	
Comments:						
		STOCK O	OF DRUGS			
	ntive stock of drug	gs available appro	priate for the			
practice site?  Are all p	harmaceutical sto	ck bottles proper	ly labeled?	NAC 639.510 NRS 585.410- 460	Yes	No
Name of product			400	Yes Yes	No No	
Manufacturer					Yes	No
Е	Expiration date				Yes	No
L	ot number				Yes	No
mislabeled, or a	dure for monitoring dulterated drugs?			NAC 639.510	Yes	No
adulterated drug	gs?				_	
Are outdated, mislabeled, or adulterated drugs removed from stock and secured in an area where they will not be used to fill prescriptions?  NRS 639.282  Yes				No		
Comments:						



### PRESCRIPTION LABELING

Do labels bear all information required?  Does the computer only issue labels with a date that is the most recent date on which the prescription was filled?			NRS 639.2801	Yes	No
			NAC 639.030	Yes	No
Expiration/discard date	on the label appears as	: <circle></circle>			
(default)	(order entry)	(handwritten)			
Comments:					
	R	ECORDS			
Are all records of pharm Training) on duty each of for prior 2 years?	• •		NAC 639.245	Yes	No
Do you keep a manual of (circle) (electronic) (hard Do you keep a manual of pharmacy management? If electronic, the record must the record must clearly identification in the present of t	ndwritten) or electronic daily work (circle) (electronic) (hast be able to be printed for the fifty the job description performance)	andwritten) he last 2 years. If electronic, ormed that day for each staff			
Are all records of the acquisition, storage and disposition of drugs accurate and complete?			NAC 639.510	Yes	No
Do all patient records include the telephone number of the patient, history of the patient, allergies, birth date and age if child, gender and relevant comments in the patient's profile in the computer or on paper? Inspector may review a random sample.			NAC 639.708	Yes	No
Does the pharmacy main schedules, refill logs, correcords for 2 years?			NRS 454.286	Yes	No
Are scheduled II controlled substances prescriptions filed separately from all other prescriptions?			NRS 639.236	Yes	No



The inspector may review a random sample of scheduled II controlled substances prescriptions and verify that they are tendered within 14 days from the date of issue. NRS 453.431 Are all telephoned prescriptions dated and initialed and documented with the name of the person who called in the prescription when transcribed to paper? NAC 639.712 No (The following are ISMP recommendations to improve practice safety) Write out all prescription information avoiding the use of error-prone abbreviations and dose designations on all phoned in scripts and notations in the computer. **ISMP** Repeat back "echo" information to the practitioner or practitioner's agent. **ISMP** Say and repeat back numbers as digits "five zero milligrams rather than 50 milligrams". **ISMP** Does the facility participate in the Controlled Substance Ordering System (CSOS – [electronic] E222 order form)? No NRS 453.251 Are schedule 2 order forms (222 or E222) properly completed? 21CFR1305.06 Yes No Are schedule 2 order forms (222 or E222) and invoices maintained separately from other records? NRS 453.246 Yes No Are schedule 3 through 5 invoices maintained separately from other NRS 453.246 records? 21CFR 1304.04h Yes No Enter the date of the last biennial inventory? NRS 453.246 Is the documentation of the biennial inventory complete? 21CFR 1304.11 No Are you complying with the current reporting requirements of the Controlled Substance Task Force? NAC 639.926 No Prescription Controlled Substance Abuse Prevention Taskforce 431 W. Plumb, Reno NV 89509 Phone: 775-687-5694 Email: ladams@pharmacy.nv.gov Pharmacy manager start date: (if changed since last inspection)



(if changed since last inspection)  Date inventory was taken:	NAC 453.475.1	Yes	No	
How are non-child resistant cap requests d (circle) (electronic) (h	ocumented and maintained? nandwritten)	NAC 639.740		
Comments:				
SECURITY				
Does any person other than authorized phathe pharmacy computer system? <b>If yes, ex</b>	HIPPA	Yes	No	
Does any person other than authorized pha any protected patient information? <b>If yes, esection.</b>		HIPAA	Yes	No
Is the pharmacy secured to prevent unauthor	NAC 639.520	Yes	No	
Is the door secured by a deadbolt or electron	NAC 639.520	Yes	No	
Can the pharmacy area be closed from the allow for different hours of operation?	remainder of the store to	NAC 639.545	Yes	No
Pharmacy alarm system provided by:		NAC 639.520		
STORE HOURS	PHARMACY HOURS	IF DIFFERENT FROM STORE HOURS		M
Monday thru Friday Saturday	Monday thru Friday Saturday			
Sunday Holidays	G 1			
Does the pharmacy sell OTC schedule 5 conarcotics) (If yes- have signature logs available for		NAC 453.490	Yes	No



Does the pharmacy deliver prescriptions outside the local area on a regular basis? (If YES- list the toll free number provided for patients to call the pharmacy for questions/counseling.)	NAC 639.708.3	Yes	No
Does the pharmacy have an internet website?  If <b>yes</b> , What is the web address?	_	Yes	No
Does the pharmacy dispense prescription medications via the website/internet?  If <b>yes</b> , is the pharmacy VIPPS (Verified Internet Pharmacy Practice Site) certified or received certification from the Nevada Board of	NRS 639.0085	Yes	No
Pharmacy?  Comments:	NAC 639.426	Yes	No
PHARMACEUTICAL TECHNICIANS AND TECHNICL	ANS IN TRAINING	3	
Does the pharmacy manager maintain documentation on site of at least 12 hours of in-service training that is required of each technician for registration renewal?  Note: Technician CE is audited every other year in the year following renewal of technician reg November 1st of even years). Make sure technician CE is current, organized and available for only have the most current records available for review. Current PTCB or Institute for Certificat certification is accepted for the 11 hours of required general CE. (Certification does not apply that is required on renewal).	eview. File old CE and law tion of Pharmacy Technicia	credits ans	and
Does the pharmacy manager maintain for each technician in training a daily training record?  Note: Technician in Training daily activities logs are reviewed yearly.	NAC 639.240	Yes	No
Does the pharmacy use a maximum of 3:1 technicians and technicians in training (in any combination) per each pharmacist working?	NAC 639.250	Yes	No



(CE & In service training records must be available on site for review by the inspector.

Technicians and Technicians in Training are required to complete 1 hour of Nevada law CE for renewal.) Comments: **IMMUNIZATION** NRS 639.065 Annual report concerning immunizations administered by pharmacists. The Board shall prepare an annual report concerning immunizations administered by pharmacists Do your pharmacists administer immunizations? No Will the data be reported by individual store or centrally? (circle) Central Individually If by individual store, please enter the email and contact information of the person who will be provide data on immunizations to the Board. .... Enter Email address below: PATIENT COUNSELING Does the pharmacy maintain documentation of acceptance or refusal of counseling on all new prescriptions? NAC 639.707 Counseling is documented by: <circle> (electronic log) (handwritten log) Does the pharmacist document counseling immediately on completion of counseling? NAC 639.707 No (The following are ISMP recommendations to improve practice safety) Use more than one patient identifier when medications are picked up. **ISMP** (i.e. Name, Address, Phone Number, Date of Birth, Other) Open the medication bottle and show the medication to the patient on all refill or new prescriptions that the pharmacist counsels on. **ISMP** REMARKS/SUGGESTIONS/TO DO'S/CITATIONS:



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	ages if you are required to provide information.
	mentation to the inspector via fax or email, attach a on form for future review on inspection.
	mation, fax to 702-486-7903 for inspections
	ce or 775-850-1444 for inspections completed by the
Reno office.	•
3. If you are required to fill out a sterile or	a non-sterile inspection form, refer to the remarks
	l remarks, suggestions, to do's or citations.
	the remarks section of the sterile addendum for any
additional remarks, suggestions, to do's	
I verify that by signing this document all person	
educational requirements met and that this phan	rmacy meets all state and federal laws.
Pharmacist on duty (signature)	Date
Pharmacist on duty (print)	
Thatmacist on duty (print)	
Inspector:	Date Inspected

Your pharmacy has been inspected by an agent of the Nevada State Board of Pharmacy. Conditions that require remedial action are listed in the remarks section above and they must be corrected within the time frame(s) stated to ensure compliance with laws and regulations governing the practice of pharmacy. I acknowledge that the noted unsatisfactory conditions have been explained to me and that I have received a copy of this Inspection report.